

Patent
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REMARKS

Claims 1, 6-9 and 10-11 are now pending. Claims 1 and 6-9 are independent claims. Claims 2-5 have been cancelled. Claim 6 has been amended. Claims 10-11 have been added. Attached hereto, captioned "**Version with markings to show changes made**", is a marked-up version of the changes made to the claims.

Claims 1-9 were rejected under 35 USC 103(a) as being unpatentable over US Patent 6,033,383 (Ginsburg '383) in view of US Patent 5,624,392 (Saab) and US Patent 5,899,899 (Arless et al.).

Specifically, the rejection takes the position that "Ginsburg teaches all of the limitations of the claims" *except (1) returning fluid to a chiller; (2) providing a coaxial catheter; (3) insulating the supply lumen; (4) the heat transfer element being metallic; and (5) the heat transfer element being helical.*

The Action then relies upon Saab as teaching "a coaxial structure", providing "a chiller that recycles spent heat transfer fluid" and "to insulate the supply lumen to prevent cooling of tissue not intended for treatment located in close proximity to the device".

Finally, the Action relies upon Arless as teaching "a metallic heat transfer element" and a "helical heat transfer element".

The Action concludes that "it would be obvious...to combine the alleged teachings of Arless and Saab with the alleged teachings of Ginsburg to "provide a means of differential heating, to reduce the amount of fluid used by recycling fluid and to prevent thermal treatment of tissue not intended for treatment" and to "enhance heat transfer capabilities".

The outstanding rejection, as applied to remaining Claims 1 and 6-9, is respectfully traversed and reconsideration is requested.

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CLAIM 1

Independent Claim 1 is directed to a method for causing hypothermia. A circulating fluid apparatus having a chiller and a flexible catheter is provided, the catheter having an inner lumen and a hollow flexible heat transfer element adjacent its distal tip. The catheter is inserted through the vascular system of a patient to place the heat transfer element in a portion of the vasculature, chilled fluid is supplied to the inner lumen of the catheter and the interior of the heat transfer element is cooled with the chilled fluid. Blood flowing in the portion of the vasculature is cooled with the heat transfer element and the fluid is returned to the chiller.

Ginsburg is directed to a temperature regulating catheter in which a "liquid medium is introduced into a lumen...[and is] altered while passing through the temperature altering region" (see Abstract) so that it may be "delivered to the target location while the fluid is within the patient" (col. 1, lines 9-11). Ginsburg is completely silent as to how a chilled fluid is supplied to the catheter and also as to how the chilled fluid exits from any of the catheter embodiments illustrated therein.

Ginsburg completely fails to teach or suggest a circulating fluid apparatus having a "chiller" that supplies chilled fluid to an inner lumen of the apparatus, the fluid then being "returned to the chiller" after cooling the heat transfer element.

Moreover, while the Examiner certainly provides an argument as to why such a modification to Ginsburg's teaching would be helpful, there is simply no evidence that Ginsburg was aware that it would overcome the problem of "reducing the amount of fluid used" by recycling fluid to a chiller, and would thus turn to the alleged teachings of Saab to implement such alleged teaching.

The Ginsburg and Saab references, at least, plainly fail to suggest the claimed combination. Applicants respectfully submit that there is clearly no factual basis in the record for the making the proposed combination, there is no prima facie case of obviousness, independent Claim 1 is patentable over any permissible combination of Ginsburg and Saab, and the rejection should be withdrawn.

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CLAIMS 6-9

Claim 6 is directed to an apparatus for causing hypothermia including a circulating unit adapted for chilling and circulating a fluid, a flexible elongated catheter, a flexible tubular outer catheter body on the catheter, a flexible fluid supply tube within the outer catheter body, a proximal end of a central lumen of the fluid supply tube being connected in fluid flow communication with an outlet of the circulating unit, a fluid return lumen within the outer catheter body, a proximal end of the fluid return lumen being connected in fluid flow communication with an inlet of the circulating unit and a flexible heat transfer element mounted to a distal end of the outer catheter body, the heat transfer element having a partially helical shape to increase the surface area available for heat transfer. Claim 7 recites the elements of Claim 6 and also recites that the return lumen "substantially surrounds the fluid supply tube" and Claims 8 and 9 recite that the heat transfer element has an at least partially "ballooned" shape and "oval" shape, respectively.

For all of the reasons discussed above with respect to independent Claim 1, Applicants respectfully submit that Ginsburg fails to teach or suggest the recited "circulating unit adapted for chilling and circulating a fluid" – in which a "proximal end of a central lumen of a fluid supply tube is *connected in fluid flow communication with an outlet of the circulating unit*" or a "a proximal end of a return lumen *connected in flow communication with an inlet of a circulating unit*", recited in each of independent Claims 6-9.

In addition, with respect to independent Claim 7, Applicants submit that Saab does *not teach or suggest* Applicants' claimed "flexible, insulated, supply tube within said outer catheter body, a proximal end of a central lumen of said supply tube being connected in fluid flow communication with an outlet of said circulating unit....wherein

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said fluid supply tube comprises a wall having insulating properties to reduce heat transfer from said return lumen to said central lumen of said fluid supply tube".

Rather, the specific section of Saab noted in the Action, col. 11, lines 27-34, describe that "multiple lumens inside catheter tube 12 could be used to circulate a cryogenic fluid while *sleeves 14 and 20 contained a heating fluid to insulate* adjacent tissue along the length of the catheter except for the distal end beyond the end of sleeve 20".

This recitation in Saab relies upon a *heating fluid to insulate*, and does *not* provide a teaching, or even a suggestion, of Applicants claimed fluid supply tube comprising a "wall", "having insulating properties", to reduce heat transfer from said return lumen to said central lumen of said fluid supply tube.

For all of the foregoing reasons, independent Claims 6-9 are believed to be clearly patentable over Ginsburg, Saab and Arless, taken in any permissible combination.

Newly added dependent Claims 10-11 are believed to be clearly patentable for all of the reasons indicated above with respect to Claims 6 and 7, respectively, from which they depend, and even further distinguish over the cited references by reciting additional limitations.

Since the Applicants have fully responded to each rejection set out in the Office Action, it is respectfully submitted that in regard to the above remarks that the pending application is patentable over the art of record and prompt review and issuance is accordingly requested. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made

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that the Examiner telephone the Applicants' undersigned attorney at (908) 518-7700 in order that any outstanding issues be resolved.

Respectfully submitted,



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IN THE CLAIMS:

Claims 2-5 have been cancelled.

Claim 6 has been amended as follows:

6. (Amended) An apparatus for [selective organ] causing hypothermia, said apparatus comprising:
- a circulating unit adapted for chilling and circulating a fluid;
 - a flexible elongated catheter;
 - a flexible tubular outer catheter body on said catheter;
 - a flexible fluid supply tube within said outer catheter body, a proximal end of a central lumen of said fluid supply tube being connected in fluid flow communication with an outlet of said circulating unit;
 - a fluid return lumen within said outer catheter body, a proximal end of said fluid return lumen being connected in fluid flow communication with an inlet of said circulating unit; and
 - a flexible heat transfer element mounted to a distal end of said outer catheter body, said heat transfer element having a partially helical shape to increase the surface area available for heat transfer.

Claims 10-11 have been added as follows.

--10. The apparatus of claim 6, further comprising is a blood flow passageway through the partially helical shape of the heat transfer element.

11. The cooling apparatus of claim 7, further comprising a blood flow passageway through the partially helical shape of the heat transfer element.--.